Remarks

This Amendment is responsive to the Office Action mailed April 6, 2001 (Paper No. 9), which Office Action was made final. Entry of this Amendment and reconsideration of the subject application in view thereof are respectfully requested.

Claims

Claims 1-24 and 26-36 were pending. Claims 1-24 and 26-36 stand rejected.

Claims 1-2, 7 and 21-22 have been amended to more particularly and distinctly define the invention. No new matter is added.

Support

Support for the amendments to the claims is either apparent or as set forth herein. Specifically, support for the recitation of "wetting a penile surface" and "placing the device in contact with the wetted penile surface" may be found in the specification at, for example, page 4, line 27 through page 9, line 20. No new matter is added.

Claim Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1-24 and 26-36 stand rejected under 35 U.S.C. § 112, first paragraph. Specifically, the Examiner asserts that

> [a]mendment with "consisting of a single layer of a filmogenic polymer" in claims 1-24 and 26-36 is new matter. Applicant has stated that support for the amendment can be found on page 7, lines 3-13, however it appears that the specification only teaches that the invention is a disk and that it does not require a backing or a release liner. It does not state that the disk is a single layer. It is submitted that a disk may have multiple layers, yet remain a disk.

Without conceding the validity of this rejection, Applicants have elected to present the invention in different terms, which terms obviate the asserted basis for this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

Claim Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 1-38 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Specifically, the Examiner asserts that

> [a] broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 5 recites the broad recitation "a vasodilator", and the claim also recites a smooth muscle relaxant, a parasymapathetic stimulator, a renin-angiotensin system inhibitor, an alpha-blocker and a calcium channel blocker which are narrower statements of the range/limitation.

Applicants respectfully traverse. Claim 5 provides a classic "Markush group" from which the "therapeutic agent" (i.e. the range/limitation) is selected. The "vasodilator" is a member of the "Markush group" not the range/limitation as the Examiner appears to be suggesting. Reconsideration and withdrawal of this aspect of the rejection are respectfully requested.

The Examiner further asserts that

> [c]laims 7 and 22 list "a phentolamine" twice.

Applicants have amended claims 7 and 22 to delete the redundant recitation of "a phentolamine". Reconsideration and withdrawal of this aspect of the rejection are respectfully requested.

The Examiner further asserts that

> [r]ecitation of "derivative" in claim 8 is indefinite since it is not specified what the derivative is. Derivatives of compounds are considered "so indefinite as to be meaningless" since they "cover such a large number of compounds, whose structures are not defined, that the specification does not support the claims" (Petrolite v. Watson, Comr. Pats. 113 USPQ 248, 1957). In the instant application, the specification does mention a cyclohexanol

> derivative but does not define what derivatives the claim is intended to encompass.

Applicants respectfully note that claim 8 was previously amended by previous amended to cancel the recitation of "derivative". Withdrawal of this aspect of the rejection is respectfully requested.

Claim Rejections under 35 U.S.C. § 102

Claims 1-8, 13, 18-24, 27 and 36 stand rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,007, 836 (Denzer). Specifically, the Examiner asserts that

> '836 discloses transdermal vasodilator systems for producing and maintaining the erection of a male penis comprising a combination of vasodilators such as prostaglandin E1, papaverine, phentolamine and polymer films (abstract, C7, L38-C8, L5; C8, L53-C9, L6). '836 also discloses the inclusion of isopropyl myristate and polyethylene glycol (C8, L41-52). The composition of '836 produce an erection "on demand, immediately before sexual intercourse" and are therefore thought to be released in less than one hour. '836 also discloses that when the vasodilator system is used in conjunction with a condom, the outer barrier is unnecessary. Therefore, the system would have only one layer (C15, L22-30).
>
> Applicant's arguments filed 1-25-01 have been fully considered but they are not persuasive. Applicant has amended the claims to include the limitation wherein the delivery device is a single layer of filmogenic polymer and argues that the cited art does not disclose a delivery device where consisting of a single layer. '836 discloses that when the vasodilator system is used in conjunction with a condom, the outer barrier is unnessary. Therefore, the system would have only one layer (C15, L22-30).

Applicants respectfully traverse. Applicants respectfully note that the claimed invention specifically does <u>not</u> include a separate adhesive applied to the claimed "disk of filmogenic polymer". Contrarily, Denzer specifically discloses that

> all the patches are provided with an adhesive on the inner, skin-facing surface [of the one or more layers]. The adhesive may be a coating sprayed on, or may be a distinct substrate layer with a tacky surface on both sides.

(See Denzer Col. 7, lines 25-43). Accordingly, the claimed invention is not anticipated by Denzer. Reconsideration and withdrawal of this rejection are respectfully requested.

Claim Rejections under 35 U.S.C. § 103

Claims 1-8, 10-11, 13, 17-27, 29 and 34-36 stand rejected under 35 U.S.C. § 103 as unpatentable over U.S. Patent No. 6,007,836 (Denzer). Specifically, the Examiner asserts that

> '836 teaches transdermal vasodilator systems for producing and maintaining the erection of a male penis comprising a combination of vasodilators such as prostaglandin E1, papaverine, phentolamine and polymer films (abstract; C7, L38-C8, L5; C8, L53-C9, L6). '836 also discloses the inclusion of isopropyl myristate and polyethylene glycol (C8, L41-52). '836 does not teach the amount of polyethylene glycol to include in the composition. However, it is submitted that this is a manipulatable parameter that would be obvious to one skilled in the art at the time of the invention to manipulate in an effort to increase or decrease flexibility of the polymer film. The compositions of '836 produce an erection "on demand, immediately before sexual intercourse" and are therefore thought to be released in less than one hour. '836 does not state whether the penile surface requires pre-wetting. It is submitted that since it not say that wetting the surface is required, no pre-wetting is necessary. It is also submitted that pre-wetting the surface would be obvious to one skilled in the art at the time of the invention to aid in adhesion of the patch to the skin, since this would aid in creating a vacuum.

Without conceding the validity of any of the Examiner's assertions, Applicants respectfully note that Denzer specifically teaches away from a delivery device which does not include an adhesive on the inner, skin-facing surface [of the one or more layers] of a transdermal patch. (See col. 7, lines 25-43). Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 1-8, 10-11, 13-14, 17-30, 34-36 stand rejected under 35 U.S.C. § 103 as unpatentable over a combination of Denzer and U.S. Patent No. 4,696,821 (Belsole). Specifically, the Examiner asserts that

> '836 is relied upon for all that it teaches as stated previously.
>
> '821 is relied upon for teaching that polyvinylpyrrolidone film is an effective means for controlling the release of an active agent when administered transdermally. '821 also teaches the inclusion of plasticizers in the polyvinylpyrrolidone films wherein the plasticizer is PEG 400. The amount of plasticizer is unclear since '821 teaches weight per volume of liquid. Should applicants traverse on the grounds that the amount of plasticizer of '821 is

> outside the instant ranges, applicants are requested to submit evidence pertaining thereto. Furthermore, it is submitted that the ranges pertaining to the amount of plasticizer is a manipulatable parameter and it would be obvious to one skilled in the art at the time of the invention to adjust the amount of plasticizer in the composition to increase of decrease the flexibility of the film.
>
> Accordingly, it would have been obvious to one skilled in the art at the time of the invention to construct the films of '836 from polyvinylpyrrolidone with the expectation that these films would control the release of drug from the patch and the motivation lying therein.

Without conceding the validity of any of the assertions made by the Examiner, Applicants respectfully note for the reasons stated above that Denzer specifically teaches away from the claimed invention. Accordingly, the combination of Denzer and Belsole does not teach or suggest the claimed invention. Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 1-8, 10-11, 13, 15-27, 29 and 31-36 stand rejected under 35 U.S.C. § 103 as unpatentable over a combination of Denzer and FR 2710649 (Postaire). Specifically, the Examiner asserts that

> '836 is relied upon for all that it teaches as stated previously.
>
> '649 is relied upon for teaching transdermal films formulated as a biodegradable patch comprising gliadin gel based on plant prolamines extracted from cereals (wheat) (abstract, p1).
>
> Accordingly, it would have been obvious to one skilled in the art at the time of the invention to construct the polymer films of '836 from gliadin with the motivation to provide a transdermal patch to treat impotence that is biodegradable and the expectation that gliadin transdermal patches are biodegradable.

Without conceding the validity of any of the assertions made by the Examiner, Applicants respectfully note for the reasons stated above that Denzer specifically teaches away from the claimed invention. Accordingly, the combination of Denzer and Postaire does not teach or suggest the claimed invention. Reconsideration and withdrawal of this rejection are respectfully requested.

FEE DEFICIENCY

☒ This Paper is believed timely filed. If an extension of time is deemed required for consideration of this paper, please consider this paper to comprise a petition for such an extension of time; The Commissioner is hereby authorized to charge the fee for any such extension to Deposit Account No. 04-0480.

and/or

☒ If any additional fee is required for consideration of this paper, please charge Account No. 04-0480.

Closing Remarks

Applicants thank the Examiner for the Office Action and believe this response to be a full and complete response to such Office Action. Accordingly, favorable reconsideration in view of this response and allowance of the pending claims are earnestly solicited.

Respectfully submitted,

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Detail of claim amendments

1. (Twice Amended) A delivery device for treatment of erectile dysfunction in a patient, consisting of a [single layer] disk of a filmogenic polymer, wherein the [single layer] disk of filmogenic polymer [comprises] contains an effective dose of a therapeutic agent suitable for treating erectile dysfunction.

2. (Twice Amended) A delivery device according to claim 1, comprising further at least one additive contained within the [single layer] disk of filmogenic polymer, wherein the at least one additive is selected from the group consisting of a stabilizer, a solubilizer, an enhancer and a plasticizer.

7. (Once Amended) A delivery device according to claim 6, wherein the at least additional therapeutic agent is selected from the group consisting of: prostaglandin, a testosterone, a yohimbine, a pentoxifylline, a trazodone, an apomorphine, [a phentolamine,] a sildenafil, a minoxidil, a misoprostol, a papaverine, a nitroglycerin, a phentolamine, a moxisylyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.

Claim 11 not listed as amended but was Entered 6/6/5 also depend cl. 9 now

21. (Twice Amended) A method of treating erectile dysfunction, comprising:

selecting a device consisting of a disk of a filmogenic polymer [and comprising] ; wherein the disk of filmogenic polymer contains [one or more] at least one therapeutic agent [agents] suitable for treating erectile dysfunction;

wetting a penile surface; and

placing the device in contact with [a] the wetted penile surface delivering the therapeutic agent to the penile surface over an effective period of time.

22. (Once Amended) A method according to claim 21, wherein in forming the disk, the therapeutic agent is selected from the group consisting of a prostaglandin, a testosterone, a yohimbine, a pentoxifylline, a trazodone, an apomorphine, [a phentolamine,] a sildenafil, a

minoxidil, a misoprostol, a papaverine, a nitroglycerin, a phentolamine, a moxisylyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.